DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2014

Skeletal Dynamics, LLC.
Ms. Ana M. Escagedo
President
8905 SW 87 Avenue, Suite 201
Miami, Florida 33176

Re: K140892
Trade/Device Name: Distal Elbow Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 31, 2014
Received: August 4, 2014

Dear Ms. Escagedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140892

Device Name: Distal Elbow Plating System

Indications For Use: The Skeletal Dynamics Distal Elbow Plating System is intended for fixation of fractures, fusions, osteotomies and non-unions of the radius and ulna, particularly in osteopenic bone.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness
Skeletal Dynamics Distal Elbow Plating System

August 25, 2014

Submitter:
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Miami, FL 33176
Tel: (305) 596-7585
Fax: (305) 596-7591
Contact: Ana M. Escagedo, Vice President
Email: aescagedo@skeletaldynamics.com

Establishment Registration Number: 3006742481

Name and Classification:

Name	Distal Elbow Plating System
Common Name	Plate, fixation, bone
Classification	21 CFR §888.3030
Product Code	HRS, HWC
Class	Class II

Predicate Devices:
DePuy Anatomic Locking Plating System (K082300)

Description of the Device:
The Skeletal Dynamics Distal Elbow System consists of various bone plates designed for fracture fixation, fusions, osteotomies and non-unions of the radius and ulna. Included in the system are titanium bone screws and pegs, cobalt chrome cannulated polyaxial screws, k-wires, and specialized instrumentation.

The Radial Head and the Proximal Ulna plates are made of medical grade titanium alloy. They are offered in left and right applications. The Proximal Ulna plate is provided in various lengths. The system is provided non-sterile and is sterilized in the user facility.

The Skeletal Dynamics Fragment Plate System is comprised of:

- Titanium alloy plates and screws
- Cobalt chrome polyaxial screws
- Stainless steel K-wires (for provisional fixation not for implantation)
- System specific instrumentation.

Intended Use:
The Skeletal Dynamics Distal Elbow Plating System is intended for fixation of fractures, fusions, osteotomies and non-unions of the radius and ulna, particularly in osteopenic bone.

Summary of Technological Characteristics / Substantial Equivalence:
The substantial equivalence of the Skeletal Dynamics Distal Elbow Plating System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging, and does not present any new issues of safety or effectiveness.

Performance Testing:
Preclinical analysis and testing demonstrated that the Skeletal Dynamics Distal Elbow Plating System is substantially equivalent to the predicate device currently marketed. Mechanical testing performed to establish equivalency included static and dynamic testing on the plates and pullout strength and torque testing on the screws. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:
The Skeletal Dynamics Distal Elbow Plating System is substantially equivalent to the predicate device identified in this premarket notification.